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PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) WO-BSX-228 / 10207709
	Application Number 10/720,176	Filed November 25, 2003
	First Named Inventor Peter Shank, et al	
	Art Unit 3738	Examiner David A. Izquierdo
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input type="checkbox"/> attorney or agent of record. Registration number _____</p> <p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>30,845</u></p> <p> Signature Thomas S. Hahn Typed or printed name (202) 662-0278 Telephone number <u>3/29/07</u> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>		

Pre-Appeal Brief Request for Review	
I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. _____ on the date shown below in an envelope addressed to: MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Dated: March 29, 2007	Signature: _____ (Thomas S. Hahn)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Peter J. Shank, et al.

Serial No.: 10/720,176

Filed: November 23, 2003

Title: **COMPOSITE STENT WITH
INNER AND OUTER STENT
ELEMENTS AND METHOD OF
USING THE SAME**

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Confirmation No.,: 4334

Group Art Unit: 3738

Examiner: David A. Izquierdo

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pending claims 2, 3, 7, 22-24 and 28-35 stand rejected under 35USC § 102(e) as being unpatentable over US Patent No. 6,556,216 (*Hossainy et al.*). These rejections are reported in the final action mailed November 29, 2006-, and they further are continued in the advisory action mailed February 13, 2007.

Specific and inherent *Hossainy et al.* disclosure failures vis-à-vis limitations recited in rejected claims are set out below. These failures are submitted as being fatal to the rejections and thereby ripe for prompt decision under the now instituted pre-appeal brief conference program. (1296 Off. Gaz. Pat. Office 67 (12 July 2005); and, as extended 1303 Off. Gaz. Office 21 (7 February 2006)).

Rejected claims 23 and 28 are independent and all other rejected claims are dependent from one or the other of these base independent claims. If both of these independent claims recite limitations that do not read on subject matter disclosed or inherent in *Hossainy et al.* then

they are not anticipated.¹ Further if these independent claims are not anticipated then their rejected dependent claims also are not anticipated.²

Among limitations recited in independent claim 23 are a composite stent comprising “a bioabsorbable stent; and a self-expanding metal stent releasably engageable within said bioabsorbable stent...” Independent claim 28 also recites a composite stent comprising a pair of stents, i.e., “an outer stent...being a bioabsorbable stent... and an inner stent...engageable with said outer stent....”

Interpretation of these recited limitations is to be made during prosecution by the Office using a standard that directs that claims be given their broadest reasonable construction “in light of the specification as it would be interpreted by one of ordinary skill in the art.”³ This direction for prosecution by the Office further is set out in the Code of Federal Regulations that directs “...claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.”⁴

Thus in determining the broadest reasonable claim construction the Office is to turn to the specification descriptions for determining the meanings of claim recited terms. On turning to the filed specification, it is explicitly and consistently found here that as recited in the rejected claims a stent is disclosed as being a structural support device for body orifices, cavities, etc. and that such a stent can be collapsed for insertion into such orifices, cavities, etc. prior to expansion as a support device.

Medical prostheses frequently referred to as stents are well known and commercially available. These devices are used within body vessels of humans for a variety of medical applications. Examples

¹ “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F. 2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)

² This conclusion as to every rejected dependent claim also reciting allowable subject matter over the asserted *Hossainy et al.* reference is premised from 35 USC § 112, fourth paragraph, where it is directed that a “claim in dependent form shall be construed to incorporate by reference all the limitations of the base claim to which it refers.” Thus, a rejected dependent claim incorporates every limitation recited in its base independent claim, including those limitations that do not read on an asserted anticipation reference.

³ *In re Am. Acad. Of Sci. Tech. Ctr.*, 367 F. 3d 1359, 1364 (Fed Cir. 2004)

⁴ 37 CFR § 1.75 (d)(1).

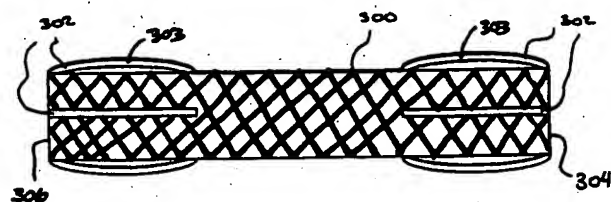
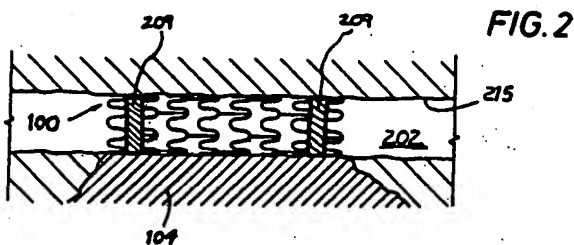
include intravascular stents for treating narrowing or contraction of body lumens (stenoses), stents for maintaining openings in the urinary biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters. (Specification, para. 0002)

Nowhere in the specification is it disclosed or suggested that stents perform as any other type of structural devices.

Turning to the final action, it there is asserted that "*Hossainy et al.* discloses a composite stent comprised of an outer stent (209) and an inner stent (100) wherein the outer stent is comprised of a bioabsorbable material (col. 4, lines 1-30) and exerts a radial force in an outward direction (col. 3, lines 44-56) and the inner stent is comprised of a metallic material (col. 2, lines 50-65) and also provides a radially outward force (col. 2, lines 60-col. 3, line 10" (Final Action, Section 4). These conclusions are maintained in the advisory action: "Examiner maintains that the bands of *Hossainy et al.* can be characterized as outer stents and therefore anticipate the outer stents of the claimed invention." Further stated in the advisory action is that the *Hossainy et al.* "outer band is comprised of the same material, and more importantly anticipates the claimed structure of the invention."

Despite these statements to the contrary, *Hossainy et al.* nowhere discloses or suggests any composite stent including *both* an inner stent and also an outer stent where both stents are structural support devices for body orifices, cavities, etc.

Two embodiments *Hossainy et al.* disclose for their so-called "composite stent" include a single stent (100 or 300, see Figs. 1-3) having either "regioselective material forming bands 209... applied to the stent 200 [sic] while the stent 200 [sic] is a compressed position" (see Fig. 2, col. 3, lines 20-22) or "a plurality of strips 302... spaced circumferentially around the stent 300" (see Fig. 3, col. 4, lines 50-52).



Hossainy et al. nowhere discloses or infers that either bands 209 or strips 302 are or could be stent structures as described in the filed specification. The strips 302, for example, from their very physical arrangements on stent 300 are precluded from in any way providing or suggesting an outer stent positioned on stent 300. The strips 302 are only interconnected via stent 300 structure, and, therefore, it only is stent 300 that can be a support device. Here there only is one stent and that is stent 300.

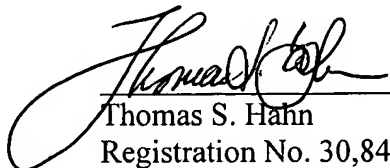
Identically, in the case of *Hossainy et al.* disclosed combinations of stent 100 and bands 209 there is only one stent, i.e., support device, and that is stent 100. Bands 209 are explicitly disclosed as being “viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time.” (Emphasis added, col. 3, lines 44-49) Nowhere do *Hossainy et al.* disclose or suggest that bands 209 “exert a radial force in an outward direction” as is stated in section 4 of the final action. Instead *Hossainy et al.* disclose, without contradiction, that bands 209 “typically exert a gradual and weak *restoring force* that avoids collapsing or substantially deforming an expanded stent over time.” (Emphasis added) In context, the restoring force that bands 209 apply about stent 100 must be without exception an inward directed force and would not include any radial force in an outward direction. Bands 209 therefore are not disclosed or suggested as being support devices for any orifices, cavities, etc. These bands 209 in exerting restoring forces, i.e., collapsing forces, on stent 100 actually prevent application of radial outward forces with their opposing directed inward forces. They, therefore, are not stents. *Hossainy et al.* only discloses a single stent and does not disclose or suggest combining a pair of stents as a composite stent.

It is submitted in view of these discussions as to *Hossainy et al.* failures to disclose or infer claimed limitations that all anticipation rejections of record should be withdrawn and that the pending claims are in condition for allowance.

This Pre-Appeal Brief is submitted without waiver as to raising the above discussed facts and law or any other facts or law in an appeal to the Board of Patent Appeals and Interferences if such is required. Concurrently filed are an executed Pre-Appeal Brief Request for Review (PTO/SB/33) and a Notice of Appeal with fee.

Respectfully submitted,

Date: March 29, 2007


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